K063691

510(k) SUMMARY

NIUINT at Fermilab's Neutron Therapy System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Northern Illinois University Institute for Neutron Therapy at Fermilab
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Contact Person: John L. Lewis, Ph.D.

JAN 3 1 2007

Date Prepared: December 12, 2006

Name of Device and Name/Address of Sponsor

Neutron Therapy Device

Northern Illinois University Institute for Neutron Therapy at Fermilab
307 Lowden Hall
DeKalb, Illinois 60115

Common or Usual Name

Neutron Therapy System ("NTS")

Classification Name

Medical Neutron Radiation Therapy System
Classification Code: IWL, 21 C.F.R. § 892.5300

Predicate Devices

Pre-1976 Neutron Therapy Device, Northern Illinois University Institute for Neutron Therapy at Fermilab.

Intended Use / Indications for Use

The NIUINT at Fermilab NTS is a preamendments medical device designed to produce and deliver a neutron beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Technological Characteristics

The modified NTS is a medical neutron radiation therapy system that provides a therapeutic neutron beam for clinical treatment. Modifications include upgrades to the Patient Treatment Chair Subsystem, the Patient Treatment Platform Subsystem, the GE CT/T 8800 Scanner Subsystem, and the Patient Treatment Simulation Software Subsystem.

Performance Data

The modified NTS Patient Treatment Chair and Patient Treatment Platform Subsystems have been in clinical use for approximately two years. The GE CT/T 8800 Scanner Subsystem has been in clinical use for approximately five years and the Patient Treatment Simulation Software Subsystem has been in clinical use for approximately twenty-five years. All subsystems demonstrate that the post-1976 modifications meet performance specifications. Performance specifications and testing information are described in Sections XVIII-XX.

Substantial Equivalence

The modified NTS is substantially equivalent to the preamendments NTS. The modified NTS has the same intended uses and similar indications, technological characteristics and principles of operation. The minor technological differences between the modified NTS and its predicate device raise no new issues of safety or effectiveness. Thus, the modified NTS is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Northern Illinois University Outreach
% Mr. Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

JAN 31 2007

Re: K063691
Trade/Device Name: Neutron Therapy System
Regulation Number: 21 CFR 892.5300
Regulation Name: Medical neutron radiation therapy system
Regulatory Class: II
Product Code: IWL
Dated: December 12, 2006
Received: December 12, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. INDICATIONS FOR USE STATEMENT K063691

The NTS is a preamendments medical device designed to produce and deliver a neutron beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063691